UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/841,078	04/25/01	LACHARRIERE	015000-430

HM22/0920

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1619	2

DATE MAILED: 09/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/841,078	Applicant(s) LACHARRIERE ET AL.	
	Examiner Lauren Q Wells	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/580,291* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-18 are pending in the current application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,658,581, over claims 1-20 of U.S. Patent No. 5,993,833, over claims 1-30 of U.S. Patent No. 6277387 and over claims 15-41 of U.S. Patent No. 6,060,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are directed toward pharmaceutical/cosmetic compositions comprising an agent which produces an irritant side-effect and a compound that is an antagonist of interleukin-1 or TNF-alpha.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4, 8, 10, 11, 13, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "solvents" in claims 2 and 11 (lines 5) is vague and indefinite, as it is not clear how all solvents, which encompasses a huge number of chemicals, produce irritant side-effects. Does this term refer to all known solvents or does it refer to something else?

(ii) The phrase "one agent which produces an irritant side-effect" in claims 1 (lines 2-3), 10 (lines 2-3) is vague an indefinite, as it is not clear what would chemically or physically define producing an irritant side-effect.

(iii) Claims 4 and 13 are vague and indefinite. Do the heterocycle and the nitrogen compound both have at least one benzene ring or does just the nitrogen have at least one benzene ring?

(iv) The term "agents which modulate the differentiation and/or the proliferation and/or the pigmentation of skin" in claims 8 and 17 (lines 4-6) is a relative term which renders the claim indefinite. The term " agents which modulate the differentiation and/or the proliferation and/or the pigmentation of skin " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-8, 10-11 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker et al. (5,039,695).

Parker et al. teach a method of using aryl or heteroaryl 1 alkyl pyrrole 2 carboxylic acid compounds in the treatment of interleukin 1 mediated conditions. Disclosed is a cream comprising 4% of an interleukin-1 antagonist (the Pyrrole 2 carboxylic acid), cetyl alcohol (alcoholic solution agent which produces irritant), glycerol monostearate PEG 40, diglycol stearate, polyethylene glycol 400, and purified water. Ascorbic acid, which is a keto acid, is disclosed as an antioxidant for use in the composition. The interleukin-1 antagonists are disclosed as comprising 0.01-15% of the composition. Oil in water emulsions, oily suspensions, aqueous suspensions, and others are disclosed as forms of the composition. See Col. 1, line 55-Col. 3, line 20; Col. 7, line 51-Col. 12, line 65.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (5,039,695) in view of Blank et al. (5,605,894).

Parker et al. fail to teach histamine antagonists and preferred active agents (see above discussion).

Blank et al. teach compositions for regulating skin wrinkles and/or skin atrophy. Disclosed is a composition comprising salicylic acid (an agent which produces an irritant side-effect), a pharmaceutically acceptable carrier, and another active agent selected from anti-inflammatory agents, benzofuran derivatives (anti-histamines), vitamins, anti-oxidants, chelating agent, retinoids, and mixtures thereof. Salicylic acid is disclosed as comprising 0.01-50% of the composition. The anti-inflammatory agents are disclosed as steroidal or non-steroidal. Solutions, lotions, ointments, emulsions, and gels are disclosed as cosmetic/pharmaceutical forms of the composition. See Col. 1, line 60-Col. 16, line 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of ~~Blank et al.~~ Parker et al. KQW by adding the histamine antagonist of ~~Parker et al.~~ Blank et al. KQW and obtain a composition comprising an interleukin 1 antagonist, an agent which produces an irritant side effect, a cosmetically acceptable medium, and a histamine antagonist because a) Parker et al. and Blank et al. both teach topical compositions for the treatment of inflammation of the skin; b) ~~Parker et al.~~ O.K. KQW teach their compounds as anti-inflammatory agents and Blank et al. teach the combination of anti-inflammatory agents and benzofuran derivatives (anti-histamine) in composition.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blank et al. (5,605,894) in view of Skotniki (4,902,800).

Blank et al. teach compositions for regulating skin wrinkles and/or skin atrophy. Disclosed is a composition comprising salicylic acid (an agent which produces an irritant side-effect), a pharmaceutically acceptable carrier, and another active agent selected from anti-inflammatory agents, benzufuran derivatives (anti-histamines), vitamins, anti-oxidants, chelating agent, retinoids, and mixtures thereof. Salicylic acid is disclosed as comprising 0.01-50% of the composition. The anti-inflammatory agents are disclosed as steroidal or non-steroidal. Solutions, lotions, ointments, emulsions, and gels are disclosed as cosmetic/pharmaceutical forms of the composition. The reference fails to teach interleukin-1 or TNF-alpha antagonists. See Col. 1, line 60-Col. 16, line 65.

Skotnicki teaches 1-substituted-4-pyrrolidinopiperidines as inhibitors of interleukin 1. These compounds are disclosed for use as anti-inflammatory agents. The compounds are disclosed as administered alone or by combining them with conventional carriers to produce a composition. The composition is disclosed for topical use for the treatment of inflammatory conditions, such as psoriasis and other inflammatory/proliferative skin disorders. See Col. 1, line 5-Col. 4, line 14.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Blank et al. by substituting the anti-inflammatory agent of Skotnicki for that of Blank et al. and obtain a composition comprising an agent which produces an irritant side-effect (i.e., salicylic acid), at least one compound selected from the group consisting of interleukin-1 antagonists and TNF-alpha antagonists (the anti-inflammatory

agents of Skotniki), and a pharmaceutically acceptable medium because a) Blank et al. and Skotnicki both teach pharmaceutical compositions comprising anti-inflammatory agents for the topical treatment of skin conditions; b) Blank et al. teach nonsteroidal anti-inflammatory agents; c) although Blank et al. disclose certain anti-inflammatory agents, he teaches that his invention is not limited to the named antiinflammatories in the disclosure.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Prior Art

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

DAMERON L. JONES
PRIMARY EXAMINER

lqw
August 21, 2001